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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/522,697
	Filing Date	27 January 2005
	First Named Inventor	Zambrana, J., et al.
	Art Unit	1626
	Examiner Name	Jason Michael Nolan
Total Number of Pages in This Submission	Attorney Docket Number	6102-000042/US/NP

ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/ Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Form 1449 IDS Documents Certificate of Mailing Return Postcard
<div>Remarks</div>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

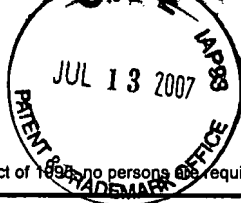
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CERTIFICATE OF TRANSMISSION/MAILING

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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Attorney Ref. 6102-000042/US/NP

Serial No: 10/522,697

Title: Novel Derivatives Of Cycloalcanodiones, Method For The Production Thereof And Their Pharmacological Applications

Filed: 27 January 2005

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Transmittal (1 page)

IDS Statement (5 pages) in duplicate

Form 1449 (7 pages)

IDS Documents 75

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of.: Zambrana, J., *et al.*
Serial No: 10/522,697
Filed: 27 January 2005
Title: NOVEL DERIVATIVES OF CYCLOALCANODIONES, METHOD
FOR THE PRODUCTION THEREOF AND THEIR
PHARMACOLOGICAL APPLICATIONS.
Group Art Unit: 1626
Examiner: Jason Michael Nolan
Confirmation No: 1882
Attorney Docket: 6102-000042/US/NP
Client Ref. No. CEPA I

13 July 2007

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner. This IDS supplements that filed in the present application on January 12, 2006.

I. **LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION**

The patents, publications and other information requested to be considered by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

II. **COPIES**

A. ☒ Submitted herewith is a legible copy of (i) each foreign patent; (ii) each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office; (iii) each unpublished U.S.

application listed below in Section IV (i.e., including the specification, claims, and any drawing of the application, or that portion of the application which caused it to be listed, including any claims directed to that portion), except for such applications filed on or after June 30, 2003, pursuant to the Waiver of the Copy Requirement in 37 C.F.R. 1.98 (OG Notice dated October 19, 2004); and (iv) all other information or that portion which caused it to be listed.

B. ☐ Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number

U.S. Filing Date

C. ☐ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search report are listed on the attached Form 1449 for consideration by the Examiner and for listing on any patent resulting from this application. If the International Search report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g).)

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. ☒ Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. ☒ A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. ☐ See the attached foreign patent office communication from a counterpart foreign application:

2. ☒ English translations are provided:

English language abstracts are provided for: WO 1996/06846 A1, WO 1997/35860 A1, WO 1999/15527 A1, and WO 2004/014915 A1.

English language abstracts are provided by the applicant for: ES 2094690 A1 and ES 2154605 A1.

English language counterparts are provided for: EP 0352613 B1, ES 2052829 T3, WO 2003/029250 A1, and ES 2238015 A1.

3. ☐ Other:

C. ☐ The following additional information is provided for the Examiner's consideration.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. ☒ The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does (do) not waive the confidentiality provisions of 35 U.S.C. § 122.

<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
10/587,792	31 July 2006	Lopez Rodriguez, M., <i>et al.</i>
11/722,786	25 June 2007	Lopez-Rodriguez, M., <i>et al.</i>
60/834,385	31 July 2006	Zambrana, J., <i>et al.</i>
60/834,384	31 July 2006	Lopez Rodriguez, M., <i>et al.</i>

V. THIS IDS IS BEING FILED UNDER

A. ☐ **37 C.F.R. § 1.97(b):** (check only one box)

- ☐ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.
- ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.
- ☐ before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).
- ☐ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. ☒ **37 C.F.R. § 1.97(c):** (check only one box)

before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. ☒ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

2. ☐ See the certification below. No fee is required.

C. ☐ 37 C.F.R. § 1.97(d):

after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. ☐ See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e): (check only one box)

The undersigned hereby certifies that:

A. ☐ each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F.R. 1.704(d) below in section VII, if applicable; or

B. ☐ no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. ☐ some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 C.F.R. 1.704(d)

The undersigned hereby states that:

☐ each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not

received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box, if applicable)

A. ☐ A check in the amount of \$180.00 is enclosed for the above-identified fee.

B. ☒ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-identified fee.

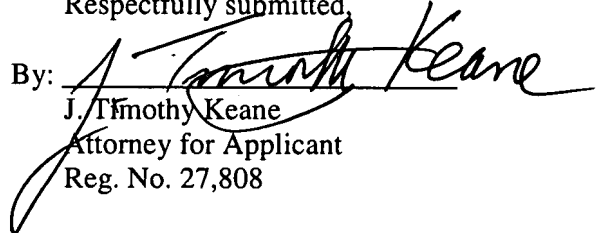
Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Respectfully submitted,

By:


J. Timothy Keane
Attorney for Applicant
Reg. No. 27,808

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FORM HDP-1449 (Based on Form PTO-1449)

PATENT AND TRADEMARK OFFICE
INFORMATION DISCLOSURE CITATION
 (Use several sheets if necessary)

Sheet 1 of 7



ATTORNEY DOCKET NO.

6102-000042/US/NP

SERIAL NO.

10/522,697

APPLICANT

Zambrana, J., et al.

FILING DATE

27 January 2005

GROUP

1626

U.S. PATENT DOCUMENTS

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
1		US 5137901 A	08/11/1992	United States	C07D 417/00	
2		US 6919360 B2	07/19/2005	United States	C07D 417/12	

FOREIGN PATENT DOCUMENTS

Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation Yes	No
3		EP 0352613 B1	04/20/1994	Europe	C07D 417/12	X	
4		ES 2052829 T3	07/16/1994	Spain	C079D 417/12	X	
5		WO 199606846 A1	03/07/1996	PCT	C07D 487/04	X (abstract only)	
6		ES 2082727 A1	03/16/1996	Spain	C07D 487/04		X
7		ES 2094690 A1	01/16/1997	Spain	C07D 207/452	X (abstract only)	
8		WO 199735860 A1	10/02/1997	PCT	C07D 154/14	X (abstract only)	
9		ES 2109190 A1	01/01/1998	Spain	C07D 451/04		X
10		WO 199915527 A1	04/01/1999	PCT	C07D 487/04	X (abstract only)	
11		ES 2129370 A1	06/01/1999	Spain	C07D 487/04		X
12		WO 199929687 A1	06/17/1999	PCT	C07D 405/14		

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM HDP-1449 (Based on Form PTO-1449) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Sheet 2 of 7	ATTORNEY DOCKET NO.	SERIAL NO.
	6102-000042/US/NP	10/522,697
	APPLICANT	
	Zambrana, J., <i>et al.</i>	
	FILING DATE	GROUP
	27 January 2005	1626

FOREIGN PATENT DOCUMENTS							
Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation Yes	No
13		ES 2154605 A1	04/01/2001	Spain	C07D 451/04	X (abstract only)	
14		WO 2003029250 A1	04/10/2003	PCT	C07D 417/12	X	
15		ES 2199086 A1	02/01/2004	Spain	C07D 487/04		X
16		WO 2004014915 A1	02/19/2004	PCT	C07D 487/04	X (abstract only)	
17		ES 2238015 A1	08/01/2005	Spain	C07D 487/04	X	
18		WO 2005075480 A1	08/18/2005	PCT	C07D 487/04		
19		EP 1674103 A1	06/28/2006	Europe	C07D 487/04		
20		WO 2006069993 A1	07/06/2006	PCT	C07D 487/04		

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)		
Ref. Desig.	Examiner's Initials	
21		Ambrossio, E. et al., [³ H]prazosin binding to central nervous system regions of male and female rats, NEUROSCI. LETT. 49(1-2):193-197 (1984)
22		Titeler, M. et al., Selectivity of serotonergic drugs for multiple brain serotonin receptors: Role of [³ H]-4-bromo-2,5-dimethoxyphenylisopropylamine ([³ H]DOB), A 5-HT ₂ agonist radioligand, BIOCHEM. PHARMACOL. 36(19):3265-3271 (1987)
23		Wong, D.T. et al., Specific [³ H]LY278584 binding to 5-HT ₃ recognition sites in rat cerebral cortex, EUR. J. PHARMACOL. 166(1):107-110 (1989)
24		Clark, R.D. et al., 1,90Alkano-Bridged 2,3,4,5-Tetrahydro-1H-3-benzazepines with affinity for the α ₂ -adrenoceptor and the 5-HT _{1A} receptor, J. MED. CHEM. 33(2):633-641 (1990)

Examiner:	Date Considered:
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EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM HDP-1449 (Based on Form PTO-1449) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Sheet 3 of 7	ATTORNEY DOCKET NO.	SERIAL NO.
	6102-000042/US/NP	10/522,697
	APPLICANT	
	Zambrana, J., <i>et al.</i>	
	FILING DATE	GROUP
	27 January 2005	1626

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)		
Ref. Desig.	Examiner's Initials	
25		Grossman, C.J. et al., <i>Development of a radioligand binding assay for 5-HT₄ receptors in guinea-pig and rat brain</i> , BR. J. PHARMACOL. 109:618-624 (1993)
26		De Vry, J., <i>5-HT_{1A} receptor agonists: recent developments and controversial issues</i> , PSYCHOPHARMACOLOGY 121(1):1-16 (1995)
27		Koh, J.Y. et al., <i>Potentiated necrosis of cultured cortical neurons by neurotrophins</i> , SCIENCE 268(5210):573-575 (1995)
28		Koroshetz, W.J. and Moskowitz, M.A., <i>Emerging treatments for stroke in humans</i> , TRENDS PHARMACOL. SCI. 17(6):227-33 (1996)
29		Lopez-Rodriguez, M.L. et al., <i>Novel benzimidazole-4-carboxylic acid derivatives as potent and selective 5-HT₃ receptor ligands</i> , BIOORG. MED. CHEM. LETT. 6(11): 1195-1198 (1996)
30		Lopez-Rodriguez, M.L. et al., <i>Synthesis and structure-activity relationships of a new model of arylpiperazines. 1. 2-[[4-(o-methoxyphenyl)piperazin-1-yl]methyl]-1,3-dioxoperhydroimidazo[1,5-α]pyridine: a selective 5-HT_{1A} receptor agonist</i> , J. MED. CHEM. 39(22):4439-4450 (1996)
31		Lopez-Rodriguez, M.L. et al., <i>2-[4-(o-Methoxyphenyl)piperazin-1-ylmethyl]-1,3-dioxoperhydroimidazo[1,5-α]pyridine as a new selective 5-HT_{1A} receptor ligand</i> , BIOORG. MED. CHEM. LETT. 6(6):689-694 (1996)
32		Matsuyama, S. et al., <i>Regulation of glutamate release via NMDA and 5-HT_{1A} receptors in guinea pig dentate gyrus</i> , BRAIN RES. 728(2):175-180 (1996)
33		Lopez-Rodriguez, M.L. et al., <i>Comparative receptor mapping of serotonergic 5-HT₃ and 5-HT₄ binding sites</i> , J. COMPUT.-AIDED MOL. DES. 11(6):589-599 (1997)
34		Lopez-Rodriguez, M.L. et al., <i>Synthesis and structure-activity relationships of a new model of arylpiperazines. 2. Three-dimensional quantitative structure-activity relationships of hydantoin-phenylpiperazine derivatives with affinity for 5-HT_{1A} and α1 receptors. A comparison of CoMFA models</i> , J. MED. CHEM. 40(11):1648-1656 (1997)
35		Lopez-Rodriguez, M.L. et al., <i>Synthesis and structure-activity relationships of a new model of arylpiperazines. 3.1 2-[omega-(4-arylpiperazin-1-yl)alkyl]perhydropyrrolo-[1,2-c]imidazoles and -perhydroimidazo[1,5-α]pyridines: study of the influence of the terminal amide fragment on 5-HT_{1A} affinity/selectivity</i> , J. MED. CHEM. 40(16):2653-2656 (1997)
36		Aguirre, N. et al., <i>MDMA ('Ecstasy') enhances 5-HT_{1A} receptor density and 8-OH-DPAT-induced hypothermia: Blockade by drugs preventing 5-hydroxytryptamine depletion</i> , EUR. J. PHARMACOL. 346(2-3):181-188 (1998)

Examiner:	Date Considered:
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EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM HDP-1449 (Based on Form PTO-1449) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Sheet 4 of 7	ATTORNEY DOCKET NO.	SERIAL NO.
	6102-000042/US/NP	10/522,697
	APPLICANT	
	Zambrana, J., <i>et al.</i>	
	FILING DATE	GROUP
	27 January 2005	1626

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)		
Ref. Desig.	Examiner's Initials	
37		Beneytez, M.E. et al., <i>Preclinical pharmacology of B-20991, a 5-HT_{1A} receptor agonist with anxiolytic activity</i> , EUR. J. PHARMACOL. 344:127-135(1998)
38		Lopez-Rodriguez, M.L. et al., <i>1-[ω-(4-Arylpiperazin-1-yl)alkyl]-3-diphenylmethylene-2,5-pyrrolidinediones as 5-HT_{1A} receptor ligands: Study of the steric requirements of the terminal amide fragment on 5-HT_{1A} affinity/selectivity</i> , BIOORG. MED. CHEM. LETT. 8:581-586(1998)
39		Nonaka, S. et al., <i>Chronic lithium treatment robustly protects neurons in the central nervous system against excitotoxicity by inhibiting N-methyl-D-aspartate receptor-mediated calcium influx</i> , PROC. NAT'L. ACAD. SCI. USA 95(5):2642-2647 (1998)
40		Suchanek, B. et al., <i>The 5-HT_{1A} receptor agonist BAY x 3702 prevents staurosporine-induced apoptosis</i> , EUR. J. PHARMACOL. 355(1):95-101 (1998)
41		Ahlemeyer B. et al., <i>The 5-HT_{1A} receptor agonist Bay x 3702 inhibits apoptosis induced by serum deprivation in cultured neurons</i> , EUR. J. PHARMACOL. 370(2):211-216 (1999)
42		Justicia, C. and Planas, A.M., <i>Transforming growth factor-α acting at the epidermal growth factor receptor reduces infarct volume after permanent middle cerebral artery occlusion in rats</i> , J. CEREB. BLOOD FLOW METAB. 19(2):128-132 (1999)
43		Lopez-Rodriguez, M.L. et al., <i>Benzimidazole derivatives. 1. Synthesis and structure-activity relationships of new benzimidazole-4-carboxamides and carboxylates as potent and selective 5-HT₄ receptor antagonists</i> , BIOORG. MED. CHEM. 7:2271-2281 (1999)
44		Lopez-Rodriguez, M.L. et al., <i>Benzimidazole derivatives. 2. Synthesis and structure-activity relationships of new azabicyclic benzimidazole-4-carboxylic acid derivatives with affinity for serotonergic 5-HT₃ receptors</i> , J. MED. CHEM. 42:5020-5028 (1999)
45		Lopez-Rodriguez, M.L. et al., <i>Design and synthesis of 2-[4-[4-(m-(ethylsulfonamido)phenyl)piperazin-1-yl]butyl]-1,3-dioxoperhydropyrrolo[1,2-c]imidazole (EF-7412) using neural networks. A selective derivative with mixed 5-HT_{1A}/D₂ antagonist properties</i> , BIOORG. MED. CHEM. LETT. 9:1679-1682 (1999)
46		Lopez-Rodriguez, M.L. et al., <i>Synthesis and structure-activity relationships of a new model of arylpiperazines. 4. 1-[omega-(4-Arylpiperazin-1-yl)alkyl]-3-(diphenylmethylene) - 2,5-pyrrolidinediones and -3-(9H-fluoren-9-ylidene)-2,5-pyrrolidinediones: study of the steric requirements of the terminal amide fragment on 5-HT_{1A} affinity/selectivity</i> , J. MED. CHEM. 42(1):36-49 (1999)

Examiner:	Date Considered:
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	6102-000042/US/NP	10/522,697
	APPLICANT	
	Zambrana, J., <i>et al.</i>	
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